

OCT - 2 2001

K012952
Special 510(k) – Device Modification
Hemashield Gold Woven Double Velour Branch Graft
August 31, 2001

Section 5

Summary of Substantial Equivalence

Summary of Modifications

As shown previously in this submission, the Branch Graft Configurations is different from the rest of the Hemashield Gold Woven Double Velour Vascular Graft product line only in the 1-4 branch configuration in which the grafts are sewn.

Substantial Equivalence

The modified vascular grafts have the following similarities to those which received previously received 510(k) concurrence:

- Identical indications for use
- Identical labeling
- Identical manufacturing processes
- Identical operating principle
- Incorporate identical materials
- Have the identical shelf-life (5 years)
- Are packaged and sterilized using identical packaging materials and processes

In summary, the Branch Graft configuration of the Hemashield Gold Woven Double Velour Vascular Graft product line described in this submission are equivalent to the predicate device.

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Summary of Substantial Equivalence, Continued

Summary of Design Control Activities

The design verification tests below are a combination of standard release tests and in-process functional tests conducted on the Hemashield Woven Double Velour Vascular Graft product line. Also included in this list are biocompatibility and shelf life tests conducted on Hemashield Woven Double Velour Vascular Grafts. There is no change to these tests or to their acceptance criteria for the Branch Graft line extension.

Test Performed		Acceptance Criteria
1	Visual Inspection – Stains	$\leq 0.05\text{mm}^2$
2	Visual Inspection – Foreign Matter	$\leq 0.03\text{mm}^2$
3	Water Permeability	Accept: if $\leq 4.0 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$ Reject: if $> 4.5 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$ Repeat test if > 4.0 and $\leq 4.5 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$ If re-test values are all $< 4.5 \text{ mL}\cdot\text{cm}^{-2}\cdot\text{min}^{-1}$ then batch is acceptable.
4	Burst	$> 399.9 \text{ lb/inch}^2$
5	Crimp	12.0 turns/inch – circular
6	Usable Length	Main Graft – $45 \pm 5\text{cm}$ Head Branches – $17.5 \pm 2.5\text{cm}$ Perfusion Branch – $22.5 \pm 2.5\text{cm}$
7	Inner Diameter	$\leq 10.0 \text{ mm}$ sizes; nominal diameter $\pm 0.5 \text{ mm}$ $> 10.0 \text{ mm}$ sizes; nominal diameter $\pm 1.0 \text{ mm}$
8	Visual Inspection – Sewing	No sewing defects
9	Air Permeability	$\leq 24.5 - 43.5 \text{ l/m}$ (depending upon size)
10	Pyrogenicity: Rabbit Pyrogen	Pass
11	Acute Systemic Toxicity: Acute Systemic Injection	Pass
12	Irritation: Acute Intracutaneous Reactivity	Pass
13	Hemocompatibility: Hemolysis	Pass
14	Cytotoxicity: ISO L929 MEM Elution	Pass
15	Mutagenicity: Ames Test (Saline extract)	Pass

Continued on next page

Summary of Substantial Equivalence, Continued

16	Subchronic toxicity: 14 day IV injection in rats	Pass
17	Implantation: ISO Muscle Implantation with histopathology (2 week)	Pass
18	Implantation: ISO Muscle Implantation with histopathology (12 week)	Pass
19	Physiochemical	Pass
20	Shelf Life Testing	Meets Product Specification after aging

All testing was done with standard test methods for these parameters. All testing showed the Branch Graft configuration is substantially equivalent to the predicate device. ***No new issues of safety or efficacy were raised. A declaration of conformity with design controls is included in Attachment 3.***

**510(k)
Statement**

A 510(k) Summary and Certification can be found in Attachment 4.

**Truthful and
Accuracy
Statement**

A certification of Truthful and Accuracy can be found in Attachment 5.



OCT - 2 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jennifer Bolton
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K012952
Hemashield Gold Woven Double Velour Vascular Graft-Branch Graft
Regulation Number: 21 CFR 870.3460
Regulation Name: Vascular graft prosthesis of 6 millimeters and greater diameter.
Regulatory Class: II
Product Code: DSY
Dated: August 31, 2001
Received: September 4, 2001

Dear Ms. Bolton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

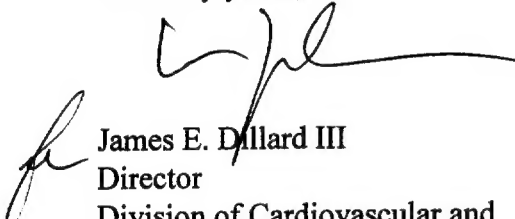
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k)
Number
(if known)

Unknown

K012952

Device
Name:

Hemashield Gold Woven Double Velour Vascular Graft
– Branch Graft

Indications
for Use

The Hemashield Gold™ Woven Double Velour Vascular Graft is indicated for use in the replacement or repair of arteries affected with aneurysmal or occlusive disease. The prosthesis is also recommended for use in patients requiring systemic heparinization prior to, or during, surgery.

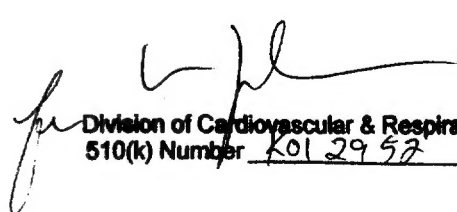
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)


Division of Cardiovascular & Respiratory Devices
510(k) Number K012952